**Purpose:** To validate equipment, methods and processes affecting the critical product attributes of the final product.

1. **Procedure**

Validation, in simple terms, is documenting that a piece of critical equipment, production process, cleaning procedure, analytical method, in-process control test procedure, or computerized system is capable of producing product that meets specifications under normal circumstances and exhibiting normal process variation. The general steps to complete a typical validation are below:

1. Identify the critical product attributes. These can be identified from historical data, and the necessary ranges for the reproducible operation should be defined. This should

include:

Defining the product in terms of its critical product attributes

Identifying process parameters that could affect the critical quality attributes of the product

Determining the range for each critical process parameter expected to be used during routine

manufacturing and process control

1. Write a validation protocol. At a minimum, the protocol will include specifics of what parameters will be tested, the acceptance criteria, and the number of process runs. The protocol will be reviewed and approved by the Quality Department and other affected areas (ie. Production).
2. Document the qualification of equipment and systems. Qualification is usually carried out by conducting the following activities, individually or combined:
   1. Design Qualification (DQ): documented verification that the proposed design of the facilities, equipment, or systems is suitable for the intended purpose
   2. Operational Qualification (OQ): documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges
   3. Performance Qualification (PQ): documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications
   4. Installation Qualification (IQ): documented verification that the equipment or systems, as

installed or modified, comply with the approved design, the manufacturer’s recommendations and/or user requirements

1. Gather data from the process runs.
2. Write a report based on the protocol that summarizes the results, comments on any deviations, draws appropriate conclusions, and includes any recommended changes to correct deficiencies.
3. **Validation Review**

At the Annual Quality Review, the need for re-validation of equipment or processes based on the data will be determined and assigned through the CAPA list generated at that meeting.

1. **Re-validation**

When any process critical equipment is modified (ie, changes in physical size, nature of operation, or sequence in the overall process) a new validation should be performed.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Revision  Number | Revision  Date | Effective  Date | Revision  Author | Quality  Approval | Production Approval | Revision Description |
| 00 | 8/20/2012 | 8/20/2012 | P. Owen | D. Durbin | J. Bumgarner | Original Document |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |